

NUCLEAR REACTOR REGULATION

EFFICIENCY ASSESSMENT

Licensing Actions

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INTRODUCTION

The Nuclear Regulatory Commission retained Arthur Andersen to provide an independent assessment of the Nuclear Reactor Regulation Office (NRR), its largest program office. Assessment objectives are two-fold – to evaluate both the effectiveness and efficiency of NRR activities. The effectiveness component of the assessment identifies those critical activities both necessary and sufficient to deliver NRR’s desired outcomes, while the efficiency component is designed to identify opportunities for generally improving the efficiency of core activities within NRR. NRC leadership commissioned programmatic assessments in response to several internal and external environmental factors. The primary factors at work in NRC’s internal environment include:

- **Intense Stakeholder Scrutiny** -- The industry is lobbying congressional leadership to challenge the NRC’s current regulatory framework. The industry would like NRC to adapt its regulatory framework to acknowledge improved reactor performance by easing burdens. Congress has also proposed reductions in the recent budget cycle and encouraged the NRC to respond to industry demands for more efficient and cost effective regulation.
- **GPRA and Others Performance Measurement Pressures** -- The Agency is also responding to mandates related to the Government Performance and Results Act (GPRA) requiring all Federal agencies to implement performance measurement and monitoring systems.
- **Increased Licensee Renewals and Transfers** -- As reactors near the end of their license life-spans, many utilities are expected to approach the Agency about renewing their licenses. As energy deregulation progresses, reactors may change ownership. This, too, will require NRR’s approval. The agency must plan ahead to find the most effective and efficient means of expeditiously processing these licensing actions.

Primary factors operating within NRR’s internal environment include:

- **Retirement of Experienced Staff During The Next Three 3 Years** – Current processes rely heavily on informal networks and experienced staff. The NRC needs to consider, and plan for, the implications of this change in its workforce.
- **Confusion About The Emerging Risk-Informed Regulatory Framework** -- According to the recent cultural survey conducted by the Inspector General’s Office, NRR staff feel unclear about the specific implications of shifting to a risk-informed regulatory framework.

This report is the result of the first NRR efficiency review. It examines Licensing Actions, the activity designed to help nuclear reactors make changes to the technical specifications that govern their operations.

The report identifies 5 processes within the Licensing Action activity area. Following observations about each process, we offer strategies and specific tactics designed to improve efficiencies within each process. Detailed process maps and descriptions of each process area can be found in Appendix A.

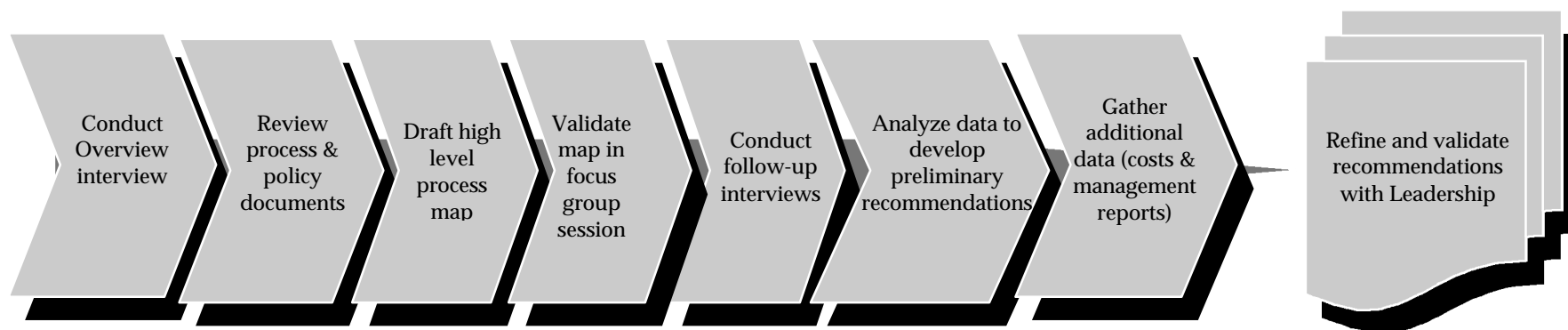
LICENSING ACTION ASSESSMENT OBJECTIVES

NRR Leadership identified Licensing Actions (LA) as the first programmatic area for assessment. Processing LAs are an important and visible component of NRR's total workload. NRR has processing targets of 1500 LAs per year. LAs are: license amendments, NRR originated orders, exemptions, reliefs, and notices of enforcement of discretion. Currently, amendments constitute approximately 60% of the LA workload. Reliefs and exemptions comprise 30% and 10% of the workload, respectively. Because amendments constitute a lion's share of the LA workload, and the processes for granting reliefs and exemptions is essentially a subset of the process for granting amendments, this review generally focuses on amendments processing.

Specific LA efficiency review objectives include:

- **Help NRR meet Licensing Actions performance targets** -- The estimated average cycle time is 56 weeks. NRR has a performance measure of completing 80% of actions in one year or less, 95% in less than two years and 100% in under 3 years. NRR has a current backlog of 2000 safety evaluations, the most critical item for granting amendments. According to NRR reports, there were at least 1200 actions in the month sampled. It is unclear whether the items in the backlog consist of items removed from inventory and/or items not yet entered into inventory.
- **Define and design in best practices as appropriate** -- The ideal process design should incorporate best practices utilized by world class organizations. Such practices include minimizing hand-offs, ensuring that all process participants add value, and standardizing wherever possible.
- **Ensure that the Licensing Actions process helps NRR meet organizational goals** -- NRR leadership recently identified four primary goals in a session facilitated by Arthur Andersen. The four goals include maintaining safety, reducing licensee regulatory burdens, increasing internal operating effectiveness and efficiency, and increasing public confidence.

The strategies and tactics included in this report are designed to help NRR rework the licensing actions process so that it better meets these objectives.

ASSESSMENT METHODOLOGY OVERVIEW

Arthur Andersen's review of Licensing Actions began in late July 1998. The Arthur Andersen team has worked closely with NRC staff to collect process data and assess the efficiency of the Licensing Actions process.

The graphic above represents Arthur Andersen's assessment methodology. Our primary data collection strategy entailed conducting eight interviews with key NRC personnel, and facilitating a focus group with a cross-section of staff responsible for processing licensing actions. These interactions yielded process data and metrics such as cycle times, to the extent that they were available.

Our secondary data collection strategy entailed examining a wide variety of process documentation including: operating budgets, Office Letters, Job Manuals, audit reports and the OIG's cultural survey. This information helped us identify additional process steps, process metrics and gauge the extent to which processing Licensing Actions is formalized.

Collected data was used to develop process maps. We first developed a high-level process overview map, which was validated during the focus group and through interviews. Once the high-level activity map was complete, we developed detailed maps for each of the five processes (Appendix A) comprising Licensing Actions. These sub-processes are:

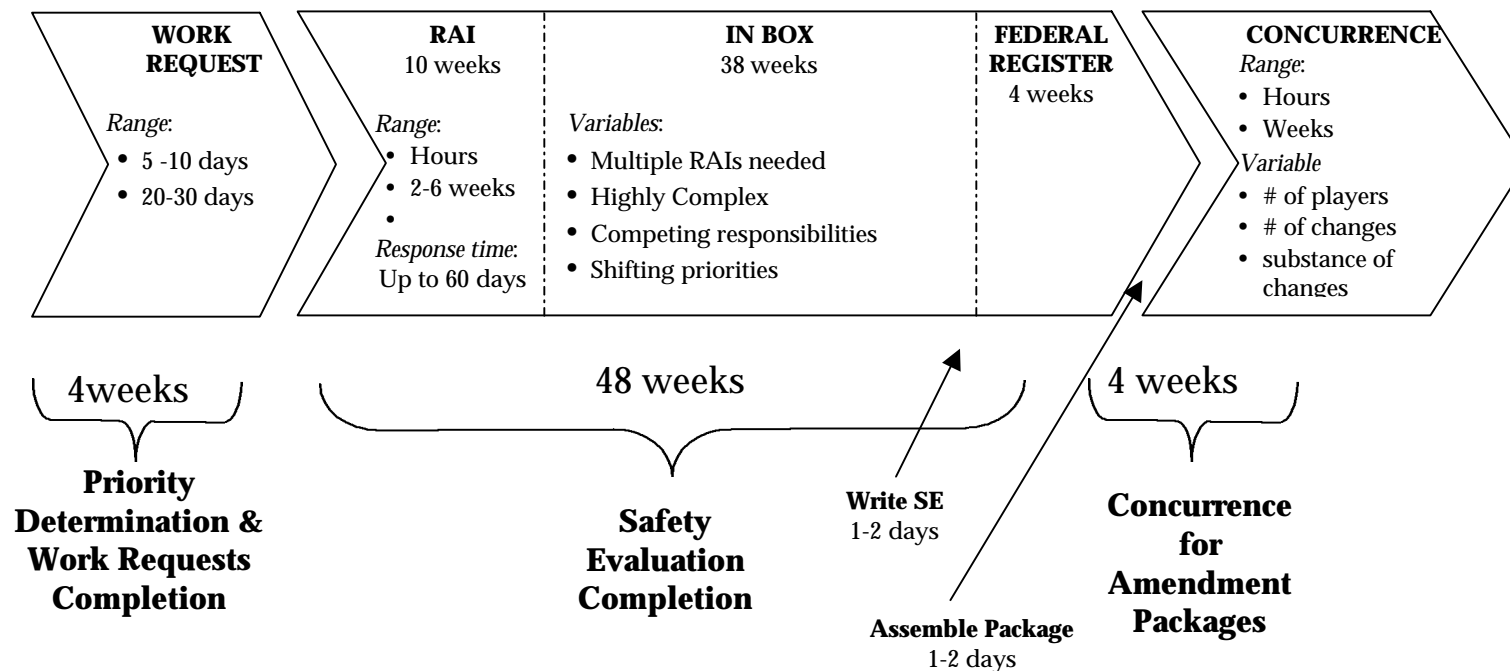
- Workload and Prioritization
- Safety Evaluation Process
- Request for Additional Information (RAI) Process
- Concurrence Process
- Public Notification Process

Process flows and metrics became one basis for formulating strategies and tactics to help NRR meet its performance objectives for Licensing Actions. These strategies and tactics are described in the following chapter.

LICENSING ACTION PROCESS OVERVIEW

After identifying the five areas for potential improvement, the team mapped each sub-process out in detail. Components were analyzed for the value they added toward meeting the process's purpose and NRR's goals, and to identify main drivers of the sub-process's cycle time.

The following picture shows an overview of each sub-process and how it relates to a high level view of the licensing actions process. It represents the break-down of total cycle time, depicts key drivers and variables per sub-process and reveals overlapping time sequences. Time ranges were gathered from interviews with NRR staff – they represent best guesses in the absence of more concrete data. For instance, this representation shows that the mandatory 30 day waiting period for public comment imposes little or no delay to overall cycle time. However, it is ambiguous as to what causes a 37 week delay for a standard amendment when it only takes 1-2 days to write up with all necessary information and no interruptions. While cycle times for issuing reliefs and exemptions may slightly vary, they generally follow the same path as issuing amendments.

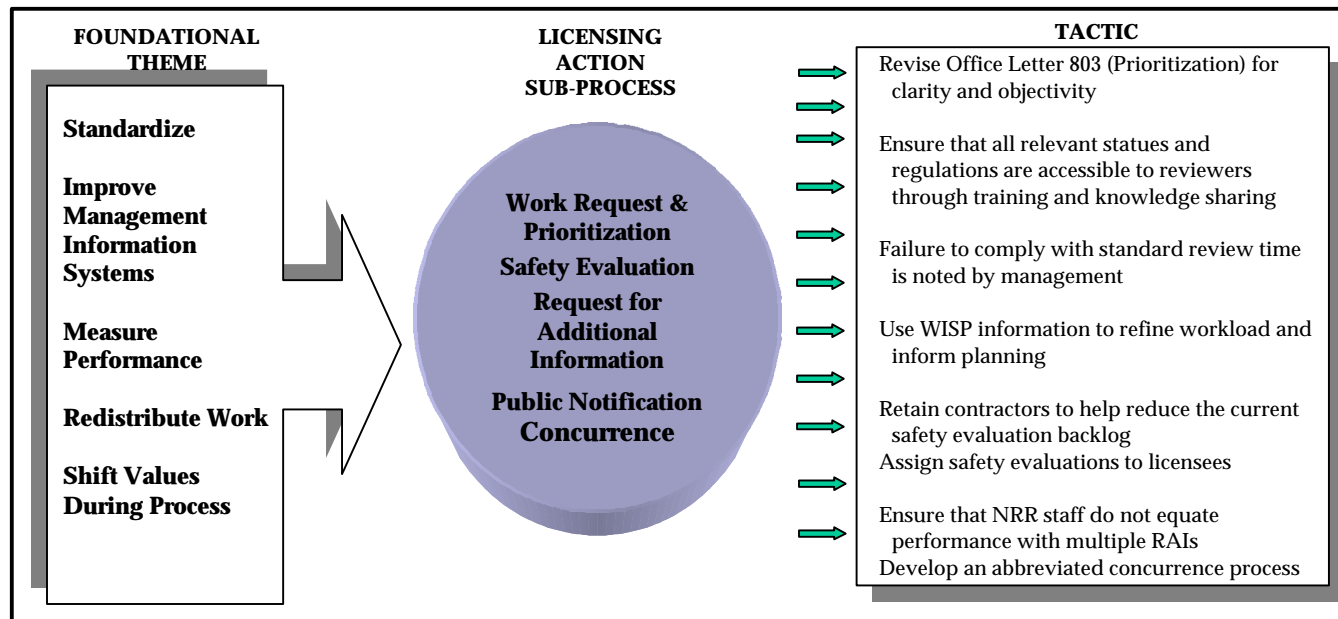
Total Average Time = 56 Weeks

OBSERVATIONS AND RECOMMENDATIONS

Analysis of key drivers to each sub-process gave rise to process observations. Through these observations, five themes emerged to bridge cycle-time related issues with recommendations and tactics for implementation. The themes are listed below and are laid in the context of desired outcomes:

- Standardize the process (clear expectations and accountability)
- Enhance Management Information Systems (basis for decision-making)
- Measure performance (reinforce expectations and accountability)
- Reallocate Work (reduced workload)
- Shift organizational values (change to “risk-informed regulation”)

As the graphic below demonstrates, the themes, drawn from observations based on key-driver analysis, may be applied through the lenses of sub-process areas. Themes are integrated with general recommendations to produce specific action steps designed to reduce sub-process cycle time, and ultimately total cycle time.



A. Priority Assignment and Work Requests Process

A1. Observations:

- Work request forms are intended to serve as contracts, but not all parties enforce this intended use of work requests
- Priorities assigned to work requests often change as a result of impending due dates
- Technical Review staff are more likely to respond to persuasive Project Managers in discussions than to numerical priority levels written on work requests
- Technical reviewers may agree to target dates they know are unrealistic
- Priorities are initially assigned according to the terms of Office Letter 803, which are subjective and flexible
- Guidelines categorize scenarios into priority levels, but NRR staff rely on networking to establish true priorities
- Communication between Technical Reviewers and Project Managers is critical to keeping work backlogs under control
- The average cycle time for a Level III priority is 6 months, the average cycle time for a Level IV priority is 12 months
- Due dates on 1/3 to 1/2 of all safety evaluations change
- The average cycle time for completing work requests is 30 days - from the moment a submittal arrives at NRC until the Technical Reviewer or Project Manager can begin conducting the safety evaluation
- The targeted cycle time for completion of work requests is 5 days
- Licensing actions constitute less than 50% of Technical Review staff's workload
- It typically takes 30 days to complete a work request – the target is 5 days
- Priorities are determined based on today's workload – they do not anticipate tomorrow's
- Priorities are informally negotiated – there are few rules and therefore minimal standards

A2. Strategy:

The work request is an output of the priority determination sub-process. Priority determination has different meanings at different levels within NRR. In the context of licensing actions, it entails determining the relative importance of one or another amendment, and formalizing this determination in a work request. Priority assignment determines the order in which licensing action amendments will be completed.

Arthur Andersen recommends that NRR clarify how priorities are determined and enforce the due dates (determined by priority assignment) agreed to in written work requests. Action steps for implementing this recommendation will help NRR complete licensing action amendments in a more timely manner.

A3. Tactical Action Steps for Implementing Strategy:

- Revisit the Office Letter that is currently used by Project Managers to determine relative priorities – make it clearer and less subjective
- Re-evaluate the information about completion timeframes associated with each priority – ensure that timeframes are realistic and based on actual performance data
- Log all work requests (within 3 days of receipt) into WISP prior to assigning priorities – produce a weekly report of all such items
- Assign responsibility for determining priorities to a small committee comprised of Project Directors and Section Chiefs – use the WISP printout during weekly meetings to set priorities for all work requests
- Develop and release an Office Letter or other policy instrument clearly describing, the limited circumstances under which changes to due dates are acceptable
- Use WISP information to refine workload forecasts and inform planning efforts

B. Safety Evaluation Development Sub-Process

B1. Observations:

- WISP's potential effectiveness as a tracking and management information tool requires further analysis.
 - Not everyone uses WISP
 - WISP has no audit trail.
- The safety evaluation sub-process has a myriad of variables and exceptions. Some variables include:
 - Prioritization and workload revisions
 - Project Managers and Technical Reviewers' familiarity with regulations
 - Complexity of the licensing action
 - Applicable regulation's latitude for interpretation
 - Experience and qualifications of Project Managers and Technical Staff
- Variations and exceptions result in varying cycle times
- Project Managers and Technical staff agree that it typically takes 1-2 days to write a safety evaluation
- The current safety evaluation backlog is 2000
- Contractors are currently used to conduct some safety evaluations, and have been more widely used in the past
- Safety evaluations take between nine months and one year to complete
- Broadly interpreting the scope and depth of safety evaluations increases the time spent completing them
- Significant time is lost in the hand-offs between Project Managers and Technical Reviewers

B2. Strategy:

Although safety evaluations typically require approximately nine months to one year to complete, Technical Reviewers reported that the time needed to develop most safety evaluations is actually one to two days. The time required to complete safety evaluations appears to be a function of several factors, including the following:

- Safety implications of proposed amendments
- Sensitivity of proposed amendments
- Interpretation of proposed amendments
- Priority assignment designated by Project Managers
- Project Managers' timing for handing off safety evaluations to Technical Reviewers
- Current NRR work priorities, ie: licensing activities, requests from NRC Commissioners
- Needs for additional information from licensees

These factors, in combination, leave NRR facing a backlog of approximately 2000 safety evaluations. If NRR is to meet its licensing actions performance targets, it must take specific actions to ensure that safety evaluations, key outputs of the Licensing Actions process, are completed more expeditiously.

B3. Tactical Action Steps for Implementing Strategy:

- Clarify the appropriate scope and depth of safety evaluations through issuance of an Office Letter or other procedural memo. A more narrowly defined scope, especially for items posing no/low safety risks, would reduce the effort required to complete safety evaluations
- Encourage Project Managers to complete no/low safety risk safety evaluations themselves – the development of a widely accessible and fully populated “knowledge base” would help by making precedents, current templates and OGC approved boilerplate language available
- Ensure that all relevant statutes and regulations are accessible to Project Managers and Technical Reviewers through training and a knowledge repository
- Assign clear responsibility for maintaining current, accurate information in the Work Information Schedule Program (WISP), and producing and distributing regular management reports about the status of safety evaluations
- Compel Project Managers, who opt to hand responsibility for safety evaluations (recorded in Work Requests) to Technical Reviewers, to turn relevant materials over in a more expeditious manner. Track and review the progress of safety evaluations in WISP
- Retain contractors to help reduce the current safety evaluation backlog

C. Written Requests for Additional Information (RAIs) Sub-Process

C1. Observations

- No standard guidelines exist for a) determining if an RAI is necessary, and b) documenting RAIs
- No boilerplate language for RAIs exists, experienced Technical Reviewers who are familiar with precedents can borrow wording
- Some Technical Reviewers have the perception that RAI's are positively correlated with thorough safety evaluations
- NRR does not proactively educate licensees about its data needs for conducting safety evaluations. Technical Reviewers believe information is accessible and licensees have a clear understanding of what information NRR needs. The only guidelines available to licensees are the Code of Federal Regulations, staff standard review plans, informal conversations with Project Managers before submitting their requests, and directives in NUREG0800
- The following factors are positively correlated with written RAIs:
 1. Thoroughness of licensee's submittals
 2. Complexity of the topic
 3. Familiarity of reviewer with regulations
 4. How much latitude regulation has for interpretation
- Despite NUDOC, Technical Reviewers often submit RAIs to section chiefs as a means of determining if relevant information already exists, making the organization dependent on informal networking to extract existing knowledge.
- The cycle time for issuing an RAI can range from a couple of days to 1.5 months (4 week average), while the target is 2 weeks
- 90% of amendments require at least one telephone call to the licensee in order to clarify their submitted safety analysis
- 30% of amendments require a written RAI
- 5-10% of amendments require multiple written RAIs
- One RAI can have multiple questions
- Licensees complete 90% of RAIs are within the required 60 day time frame
- Technical Reviewers and/or Project Managers typically take about 4 weeks (ranges from 2 to 6 weeks) to put together an RAI and get the necessary approvals to send it out

C2. Strategy

Writing Requests for Additional Information (RAIs) and waiting for licensees to respond to such requests comprises a significant percentage of the total time required to conduct safety evaluations. NRR should take specific measures to reduce the total number of written RAIs and shorten the time currently spend developing, reviewing and waiting for licensee responses to RAIs.

C3. Tactical Steps for Implementing Strategy:

The number of written RAIs can be reduced by taking the following actions:

- Providing standard instructions/requirements to licensees more precisely characterizing the information necessary to conduct thorough safety evaluations
- Ensuring that Technical Reviewers and Project Managers understand that high numbers of written RAIs are not viewed by NRR management as indicators of strong performance
- Relaxing standards prescribing when written RAIs are necessary, allowing Technical Reviewers and Project Managers to gather as much information as possible via telephone calls
- Discouraging the use of written RAIs through policy memos or Office Letters in preference for telephone calls
- Ensuring that NRR staff do not equate successful performance with multiple RAIs
- Minimizing the process for approving written RAIs for distribution to licensees
- Reducing the time allotted for licensees to respond to written RAIs

D. Federal Register Notification and Hearings Sub-Process

D1. Observations:

Most of the sub-process steps within Federal Register Notification and Hearings are governed by statute, and would be difficult to change. Less than 1% of items noticed in the Federal Register generate public comment: an even smaller subset require hearings. Additionally, this sub-process occurs simultaneously with RAIs and development of Safety Evaluations. Finally, policies governing this sub-process include considerations for emergency situations. Given that this sub-process does not currently delay the great majority of licensing actions, the effort and political capital required by NRR to make significant changes to this sub-process will not yield commensurate benefits.

- Almost all of this process is dictated by statute
- Almost none of the backlog is attributable to noticing
- The licensing assistant, who ultimately submits notices to the Federal Register, can do so in 2 week batches or one at a time
- Both the licensing assistant and OGC check for appropriate noticing in the final amendment package

E. Concurrence Sub-Process

E1. Observations:

- While the process was designed to ensure that all perspectives are considered, many perspectives are represented more than once. For example:
 - 3 levels of technical reviews
 - Secretaries and Licensing Assistants both check for editorial points and consistent format.
 - OGC and licensing assistants check the amendment package for appropriate references and verify the legal noticingProcedures were followed exactly
- The Concurrence cycle typically takes from 2 weeks to 1 month
- Perceptions of who is responsible for hold-ups differ:
- OGC's cycle for reviewing a licensing action is 7 days to 2 weeks
- Concurrence reviews typically require about 1 day per person within the chain
- Many variables and exceptions drive the concurrence sub-process
 - We received inconsistent information regarding the order of the concurrence process
 - OGC's priorities for concurrence reviews are dominated by about 50% "urgent" items
 - Licensing Assistants' roles center around noticing and concurrence, but responsibilities vary according to the Project Managers he/she supports
 - Time is a crucial factor for order of concurrence process and completion. For example, sometimes OGC sees licensing actions before the Project Director, depending on urgency
- Amendments undergo approximately nine reviews
- When substantive changes are made, the concurrence process is restarted
- Some packages are sent through the concurrence process three to four times
- Informal mechanisms are used to track progress of licensing actions through the concurrence process

E2. Strategy

The current concurrence process for amendments requires nine approvals. One process participant, the Project Manager, reviews and approves each amendment package on three separate occasions. The extent to which each process participant in the concurrence chain contributes unique insight is unclear. Standardization and reevaluation of the value added by each process participant could reduce the time currently required for concurrence packages to make their way through the process. NRR should take specific actions to streamline the concurrence process.

E3. Tactical Steps for Implementing Strategy:

- Maximize the use of OGC approved “boilerplate” language and templates for amendment package components
- Ensure that Project Managers and Technical Reviewers have simplified access to a complete set of precedents, OGC approved “boilerplate” language and templates
- Clearly delineate the role and purpose of each process participant in the concurrence chain
- Minimize the number of process participants in the concurrence chain
- Develop an abbreviated concurrence process for items posing reduced safety and/or legal risks
- Develop an abbreviated concurrence process for items utilizing the most current OGC approved boilerplate language of templates
- Issue a policy directive about limiting “edits” from process participants to substantive matters
- Limit the time allotted for reviews conducted by each process participant – ensure that failure to comply with standard review times is noted by management

CONCLUSION

This section focuses on the potential impact of the recommendations presented in this report. Each recommendation is measured by impact on three NRR objectives identified earlier in this report: increased performance, use of best practices, and alignment with organizational goals. Additionally, each recommendation is accompanied by a measure of potential impact, “High”, “Medium”, or “Low” with estimations of the ease with which the recommendation can be implemented, and the expected benefits.

The following matrix provides a means to judge the recommendations individually as they relate to impact on the improvements in licensing action cycle time.

PRIORITIZATION				
Tactical Action Steps	Performance Goal	Best Practice	Organization Goal	Estimated Return on Investment
Revisit use of Office Letter that is currently used by Project Managers to Determine Relative Priorities – make it clearer and less subjective		✓	✓	High <ul style="list-style-type: none"> • Difficult to do - complex topic • High yield with better managed workload priorities
Re-evaluate the information about completion timeframes associated with each priority – ensure that timeframes are realistic, based on actual performance data	✓		✓	Medium <ul style="list-style-type: none"> • Difficult to do with current system – information is scarce • Strong payoff in terms of better planning
Log all work requests (within 3 days of receipt) into WISP prior to assigning priorities – produce a weekly report of all such items	✓	✓	✓	Medium <ul style="list-style-type: none"> • Difficult to do with current system – takes FTEs and discipline • Good effort to help understand and plan work load, increases accountability too
Assign responsibility for determining priorities to a small committee comprised of Project Directors and Section Chiefs – use the WISP printout during weekly meetings to set priorities for all work requests	✓	✓	✓	High <ul style="list-style-type: none"> • Moderately easy to do – time consuming though • High yield in focusing decision making at appropriate levels and enhancing communication
Develop and release an Office Letter or other policy instrument describing, clearly, the limited circumstances under which changes to due dates are acceptable	✓	✓	✓	Medium <ul style="list-style-type: none"> • Difficult to codify exemptions • High yield in planning workload and assessing status
Use WISP information to refine workload forecasts and inform planning efforts	✓		✓	High <ul style="list-style-type: none"> • Easy to do – if system is up to date • High payoff in better information supporting planning

Safety Evaluation				
Tactical Action Steps	Performance Goals	Best Practice	Organization Goals	Estimated Return on Investment
Have licensee conduct safety evaluations	✓	✓	✓	High <ul style="list-style-type: none"> • Difficult to change process • High yield in cycle time for processing
Clarify appropriate scope and depth of safety evaluations through issuance of an Office Letter or other procedural memo – a more narrowly defined scope, especially for items posing no/low safety risks, would reduce the effort required to complete safety evaluations	✓	✓	✓	High <ul style="list-style-type: none"> • Difficult to explicitly define scope and depth • High yield in reduced cycle times for processing
Encourage Project Managers to complete no/low risk safety evaluations themselves – the development of a widely accessible and fully populated knowledge base would help by making precedents, current templates and OGC approved boilerplate language available		✓	✓	Medium <ul style="list-style-type: none"> • Big investment • High yield if PMs do SE themselves
Ensure that all relevant statutes and regulations are accessible to PMs and Technical Reviewers through training and a knowledge base	✓	✓	✓	Low <ul style="list-style-type: none"> • Difficult to do – knowledge base is a big investment • Low yield
Assign clear responsibility for maintaining current, accurate information in the Work Information Schedule Program (WISP), and producing and distributing regular management reports about the status of safety evaluations		✓	✓	Medium <ul style="list-style-type: none"> • Moderately easy to do – requires FTE and discipline • Moderate yield in improved monitoring, planning information and accountability
Compel Project Managers, who opt to hand responsibility for safety evaluations (recorded in Work Requests), to Technical Reviewers, to turn relevant materials over in a more expeditious manner. Track	✓		✓	High <ul style="list-style-type: none"> • Easy to do • High yield in reduced cycle time through better

and review the progress of safety evaluations in WISP				access to materials for Tech Reviewer and increased accountability
Retain contractors to help reduce the current safety evaluation backlog	✓	✓		High <ul style="list-style-type: none"> • Moderately difficult if budget is restricted • High yield - processed items

Requests for Additional Information (RAIs)				
Tactical Action Steps	Performance Goals	Best Practice	Organization Goals	Estimated Return on Investment
Provide standard instructions /requirements to licensees more precisely characterizing the information necessary to conduct thorough safety evaluations		✓	✓	High <ul style="list-style-type: none"> • Low level of effort • High yield if licensees write more complete safety analysis
Ensuring Technical Reviewers and Project Managers understand that high numbers of written RAIs are not viewed by NRR management as indicators of strong performance	✓		✓	Medium <ul style="list-style-type: none"> • Easy to do – policy memo • Moderate yield – could cut the number of RAIs
Allowing Technical Reviewers and Project Managers to gather as much information as possible via telephone calls (as opposed to written RAIs)	✓	✓	✓	Medium <ul style="list-style-type: none"> • Moderately easy to do – policy memo • High yield in reducing cycle time
Minimizing the process for approving written RAIs for distribution to licensees	✓	✓	✓	High <ul style="list-style-type: none"> • Easy to do • High yield in shortened RAI time
Reducing the time allotted for licensees to respond to written RAIs	✓			Low <ul style="list-style-type: none"> • Difficult to do – may be risky • Moderately low yield in reduced cycle time

Concurrence				
Tactical Action Steps	Performance Goal	Best Practice	Organization Goal	Estimated Return on Investment
Maximize the use of OGC approves “boilerplate” language and templates for amendments package components	✓	✓	✓	High <ul style="list-style-type: none"> Development may be difficult Could save time
Ensure that Project Managers and Technical Reviewers have simplified access to a complete set of precedents, OGC approved “boilerplate” language and template	✓	✓	✓	High <ul style="list-style-type: none"> High Level of Effort with knowledge base Standardization will reduce reviews and cycle times
Develop an abbreviated concurrence process for items utilizing the most current OGC approved boilerplate language of templates	✓	✓	✓	High <ul style="list-style-type: none"> Low level of effort Standardization will reduce errors and need for some levels of review
Minimize the number of process participants in the concurrence chain	✓	✓	✓	High <ul style="list-style-type: none"> Easy to complete Reduced cycle times from multiple reviews
Develop an abbreviated concurrence chain for items posing reduced safety and / or legal risks	✓	✓	✓	High <ul style="list-style-type: none"> Easy to complete Value added review of items needing more focus
Issue a policy directive about limiting “edits” from process participants to substantive matters.	✓	✓	✓	Medium <ul style="list-style-type: none"> Easy to do Moderate yield in reduced cycle time
Limit the time allotted for reviews conducted by each process participant – ensure that failure to comply with standard review times is noted by management	✓	✓	✓	Medium <ul style="list-style-type: none"> Difficult to complete with current lack of management information system monitoring could help enforce accountability

APPENDIX A - PROCESS MAPS

The following five process maps represent the current flow of licensing information, as documented through our review of the NRC– licensing actions. Each process flow has been validated with the NRC personnel through a process of focus groups and interviews to ensure accuracy.